

SUPPORT FOR THE AMENDMENTS

Claims 1-6, 20, 22-24, and 27 were previously canceled.

Claims 7, 13, 28, and 34 have been amended.

Claims 7 and 28 have been amended to specify the pH of the antibacterial composition as falling between 1.5 and 4.5. Support for this amendment can be found on page 19, lines 2-5. The amendments to Claims 7, 13, 28, and 34 and the specification to replace “strong basic acid salt” with “acid salt of a strong base” is to correct an error arising in the translation of the present application. Support for this amendment can be found in the original Japanese language specification at the corresponding positions, as well as the concrete examples of the intended compounds appearing at page 17, lines 6-16 of the English translation.

No new matter has been added by the present amendments.

REMARKS

Claims 7-19, 21, 25, 26, and 28-43 are pending in the present application.

The rejection of Claims 7-19, 21, 25, 26, and 29-43 under 35 U.S.C. §103(a) over Imazato et al is obviated in part by amendment and traversed in part.

At the outset, Applicants wish to note that Claims 7 and 28 have been amended such that the pH of the antibacterial composition to be applied to teeth and cured or polymerized is between 1.5 and 4.5.

Imazato et al is cited as allegedly disclosing an antimicrobial dental composition. However, there are two features of the present invention that distinguish the claimed invention from Imazato et al.

The first such essential feature of the invention in Claims 7 and 28 is that the antibacterial composition contains the specific basic compound (e). The addition of the basic compound (e) to an antibacterial composition of the components (a), (b), (c) and (d) remarkably improves the storage stability and antibacteriability of the composition (See page 16, lines 21-25 of the present specification).

The remarkable improvement flowing from the inclusion of the basic component (e) is demonstrated in Table 2 (page 38) of the present specification. For the Examiner's convenience, Table 2 is reproduced below in relevant part:

Table 2

| | | Blend Ratio (wt. %) | | | | |
|---|---------------------------------|---------------------|-----------|-----------|-----------|-------------|
| | | Example 6 | Example 7 | Example 8 | Example 9 | Comp. Ex. 8 |
| Antibacterial Composition | MDPB | 3 | 3 | 3 | 3 | 3 |
| | MDP | 10 | 10 | 10 | 10 | 10 |
| | HEMA | 43.5 | 43.5 | 43.5 | 43.5 | 43.5 |
| | Distilled water | 43.5 | 43.5 | 43.5 | 43.5 | 43.5 |
| | TMDPO | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| | TEA | 2 | - | - | - | - |
| | NaHCO ₃ | - | 2 | - | - | - |
| | LiOH | - | - | 2 | - | - |
| | H ₂ KPO ₄ | - | - | - | 2 | - |
| (1) Antibacterial Property (Cell Death Percentage: %) | | | | | | |
| Concentration | 20% | 100 | 100 | 100 | 100 | 100 |
| | 10% | 100 | 100 | 100 | 100 | 91 |
| | 5% | 100 | 100 | 100 | 100 | 68 |
| | 2% | 82 | 91 | 90 | 88 | 48 |
| | 1% | 66 | 70 | 72 | 68 | 12 |
| (2) Adhesiveness (MPa) | | | | | | |
| | Bovine enamel | 15.8 | 15.9 | 15.6 | 15.1 | 18.1 |
| | Bovine dentin | 14.6 | 15.0 | 15.1 | 15.2 | 15.6 |
| (3) Storage Stability (at 50°C for 1 month) | | | | | | |
| Discoloration | ΔL^* | 0.4 | 0.3 | 0.5 | 0.5 | 0.4 |
| | Δb^* | 0.8 | 0.9 | 1.0 | 0.8 | 1.0 |
| | Visual check | colorless | colorless | colorless | colorless | colorless |
| Adhesiveness | Bovine dentin | 14.1 | 14.4 | 14.3 | 14.2 | 6.9 |

Examples 6-9 in Table 2 correspond to the method of the present invention wherein one of triethanolamine (TEA), NaHCO₃, LiOH, and H₂KPO₄ are used, respectively. Comparative Example 8 corresponds to the method of Imazato et al wherein a basic compound defined by (e) is omitted.

As evidenced by Table 2, the antibacterial compositions comprising MDPB, MDP, HEMA, distilled water, TMDPO, and any of an aliphatic amine, an alkali metal hydroxide or a strong basic acid salt (Examples 6 to 9) completely killed the cells of *Streptococcus mutans* even when the amount of MDPB therein was about 3% by weight of the composition and the concentration of the composition was 5%. In addition, the adhesiveness of these antibacterial compositions was good; and even after stored in a thermostat at 50°C for 1 month, the compositions did not discolor when observed visually, and their bonding strength to dentin lowered only slightly.

In contrast, when the same composition was prepared with the exception of the basic compound (see Comparative Example 8, i.e., Imazato et al), the antibacterial composition could not completely kill the cells of *Streptococcus mutans* even when its concentration was 10%. In addition, when stored in a thermostat at 50°C for 1 month, the bonding strength of the composition to dentin was significantly reduced. Such a result is neither disclosed nor suggested by Imazato et al.

Applicants again submit that Imazato et al does not offer any suggestion or motivation to modify its disclosure to include a specific basic component as defined in (e) of the present claims. Further, Applicants submit that the data above are sufficient to rebut even a *prima facie* case of obviousness if such a case could properly be made.

To this end, the Examiner recognizes that the disclosure of Imazato et al fails to disclose or suggest the presence of a base, such as sodium, in the dental composition. The Examiner attempts to discount this deficiency by alleging, that it is well-known to provide compositions having suitable pHs to biological environment (See from page 4, line 21 to page 5, line 3 of the Office Action mailed June 29, 2006). To support this assertion, the Examiner cites US 5,770,182 (Fischer et al) and states that it is known that compositions

adapted for physiological use approximates to physiological pH (See page 5, lines 13-15) of the Office Action mailed June 29, 2006).

This leads to the second distinction between Imazato et al and the present invention - the pH of the antibacterial composition of the present invention is between 1.5 and 4.5. The specific pH range of the present invention improves the storage stability, antibacteriability and adhesiveness at the same time (See from page 18, lines 20 to page 19, lines 5 of the present specification).

With respect to the Examiner's cited reference, it should be noted that this disclosure fails to provide the skilled artisan with any motivation to reduce the pH of the antibacterial composition of the present invention for at least two reasons. First, the composition of US 5,770,182 is a *sustained release dental composition*, such as tooth bleaching or fluoride-containing composition. In contrast, the composition of the present invention is totally different from that of US 5,770,182 at a point of etching tooth with acid (the pH of the composition of the present invention falls between 1.5 and 4.5).

Second, the pH in US 5,770,182 is specifically disclosed as being in a range *from about 5 to about 7* (See abstract of US 5,770,182), because the composition is used not to injure a tooth. Such a disclosure would actually lead the artisan away from the claimed range of between 1.5 and 4.5 rather than toward such a range. It is important for a dental bonding material, such as that used in the present invention, to acidify the dental bonding material, because of improving adhesive strength by etching of a tooth with acid.

The present invention improves the storage stability, antibacteriability and adhesiveness at the same time by not only addition of the specific bases, but also the adjustment of the specific range of pH. Imazato et al and Fischer et al do not disclose or suggest that the addition of a specific base to a dental bonding material and the adjustment of pH, much less

the remarkably improvements the storage stability, antibacteriability and adhesiveness flowing therefrom.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejections of: (a) Claims 7-19, 21, 25, 26, and 29-43 under 35 U.S.C. §112, first paragraph (written description), and (b) Claims 7-19, 21, 25, 26, and 29-43 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Claims 7, 13, 28, and 34 and the specification have been amended to replace “strong basic acid salt” with “acid salt of a strong base” is to correct an error arising in the translation of the present application. Support for this amendment can be found in the original Japanese language specification at the corresponding positions, as well as the concrete examples of the intended compounds appearing at page 17, lines 6-16 of the English translation. These examples include:

lithium carbonate, sodium carbonate, potassium carbonate, lithium hydrogencarbonate, sodium hydrogencarbonate, potassium hydrogencarbonate, sodium formate, sodium hydrogenoxalate, sodium acetate, potassium acetate, sodium propionate, sodium borate, sodium dihydrogenphosphite, potassium dihydrogenphosphite, sodium dihydrogenphosphate, potassium dihydrogenphosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate.

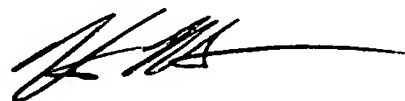
In view of the present amendment, Applicants submit that the claims and the specification meet the requirements of 35 U.S.C. §112, first and second paragraphs. Accordingly, withdrawal of these grounds of rejection is requested.

In the Office Action mailed June 29, 2006, the Examiner cites US 5,770,182 (Fischer et al) on page 5 in support of the rejection over Imazato et al. However, the Examiner does not list US 5,770,182 (Fischer et al) on form PTO-892. Accordingly, in order to make US 5,770,182 (Fischer et al) officially of record, Applicants submit herewith a form PTO-1449 listing this reference. Since this reference was first cited by the Examiner no fees are believed to be necessary and, as such, no fees have been paid. In the event that the Office determines that the government surcharge for late filing of an Information Disclosure Statement is necessary, the Examiner is requested to disregard the enclosed form PTO-1449 and to list US 5,770,182 (Fischer et al) on an appropriate form PTO-892.

Applicants submit that the present application is now in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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